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Dr. Stephen Hahn
Commissioner, Food
and Drug Administration

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Webinar

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Vice Chairman, The Economic Club of New York
Retired Chairman, Citigroup

Introduction

Good afternoon and welcome. This is Barbara Van Allen, President of The Economic Club. And we're delighted to get started right now. I'm going to turn it over to Vice Chair, Mike O'Neill. Mike.

Vice Chairman Michael O'Neill: Thanks Barbara. Good afternoon and welcome to the 547th meeting of The Economic Club of New York in our 113th year. I'm Mike O'Neill, Vice Chairman of the Club and retired chairman of Citigroup. The Economic Club of New York is one of the nation's leading nonpartisan forums for discussions on economic, social and political issues. This mission is as important today as ever as we continue to bring people together as a catalyst for conversation and innovation. We proudly stand with all communities seeking inclusion and mutual understanding.

A special welcome to guests of our members and members of The Economic Clubs of Chicago and Washington, D.C. who have also been invited to join the webinar today as well as members of The Economic Club's 2020 Class of Fellows. Before we begin, I'd again like to thank our healthcare workers and our other frontline workers for all they do, particularly during these challenging times, to keep us healthy and safe.

I'm now delighted to introduce Dr. Stephen M. Hahn, who was sworn in as the 24th Commissioner of Food and Drugs on December 17, 2019. Dr. Hahn is a dedicated

clinician, having trained in both medical oncology and radiation oncology. In his previous leadership roles, he has always carefully balanced executive management with clinical time to continue to serve oncology patients, his true passion.

Prior to joining the FDA, Dr. Hahn served as the Chief Medical Executive at the University of Texas MD Anderson Cancer Center, a facility that cares for more than 140,000 patients a year. Before joining MD Anderson, he served as chair of the Radiation Oncology Department at the University of Pennsylvania's Perelman School of Medicine from 2005 to 2014.

Dr. Hahn earned the rank of commander in the U.S. Public Health Service Commission Corps while at the National Institute of Health's National Cancer Institute where he also completed a fellowship in medical oncology and a residency in radiation oncology. He also completed a residency in internal medicine at the University of California at San Francisco.

The format today is a conversation which I am fortunate to be moderating and it will end promptly at 1:00. I remind everyone that there is media on the line so this is an on the record conversation.

Conversation with Dr. Stephen Hahn

VICE CHAIRMAN MICHAEL O'NEILL: Well, Dr. Hahn, thank you for taking the time to be with us. As we said offline, getting this job on December 2019, wow, what a baptism of fire. How are you handling it?

DR. STEPHEN HAHN: Well, Mike, it's an absolute pleasure to be here today. Thank you for having me. Yes, it certainly was trial by fire, no question about it. As you mentioned, I was sworn in on December 19 and I intended to spend my first 90 to 100 days learning about the organization. That's what a leader does. So I certainly spent the first six weeks doing that and then, of course, Covid-19 came to our shores. So at the same time learning about an organization that's complex but really terrific, but also addressing this issue from a leadership point of view. So it's certainly been a challenge for everyone.

FDA is at the forefront of the nation's response to this because we are needing to get medical products into the hands of providers and consumers. But I can tell you one thing that I've relied upon is the incredible dedicated 18,000-plus staff at FDA who are incredible, dedicated, and experienced public servants and have really worked around the clock to try to help get medical products in the hands of the American people.

VICE CHAIRMAN MICHAEL O'NEILL: Great. It sounds terrific. Could you quickly go over the duties of the, the mission of the FDA? Obviously, we're going to want to focus on Covid-19 during this conversation but just to give our members a sense for what your responsibilities are.

DR. STEPHEN HAHN: We are a public health regulatory agency. The products we regulate represent about 20% or 1 in 5 of every dollar that American consumers spend. The span of that is devices, laboratory tests for example, but CAT scanners, radiologic devices for delivering radiation for cancer. It also spans things like drugs, all pharmaceuticals, over the counter drugs, as well as vaccines and biologic cellular therapy. And then one really important area, Mike, is food because that's the "F" in FDA. And we are responsible for about 80% of America's food supply. The other 20% is the Department of Agriculture. And really the safety and security of the American food supply is a national security issue. So we, as you can tell, during the Covid-19 crisis where basically it was like seven Thanksgivings strung together in terms of demand for food, that system had a lot of stress and we spent a lot of time making sure that it was safe and secure.

VICE CHAIRMAN MICHAEL O'NEILL: It sounds terrific. Let's turn to the topic du jour here, the Covid-19 pandemic. You know the surges in the south and southwest are discouraging and I guess one has to question the ability and the willingness of the

nation to deal with the spread of this which makes the development of therapeutics and ultimately a vaccine particularly critical. Where are we on both of those?

DR. STEPHEN HAHN: So you're absolutely right. They have to be in parallel tracks. I'll take therapeutics first so treatments for Covid-19. I think this is a great reflection of the incredible private sector that we have in this country, the partnership that we've developed between government and public sector, the academic centers who have helped facilitate this because over the last four to five months we have seen new tools in the toolbox for providers. You mentioned a short seven months ago I was one of those providers. And I want to echo what you said about thanks to those great heroes because they really are doing incredible work for people. But we have therapies now that we didn't have a couple of months ago, and I'll walk through those, but the pipeline is also robust, Mike. And I can tell you about some of that as well.

So we have a drug called remdesivir. And really in record time it went through a Phase III randomized, clinical trial. That's an antiviral drug that affects the virus directly. And that was shown to reduce hospital stay for very sick Covid-19 patients. We also have a steroid, very common, inexpensive drug called dexamethasone, which was shown in a trial to reduce mortality from Covid-19 in sick patients by 30%, which is really a remarkable result.

We have something called convalescent plasma, a very large program in this country that is run by the Mayo Clinic which allows us now – we have over 50,000 people enrolled in that, over 35,000 folks have been treated with that. What that is, is that you take plasma, the antibodies from someone who has recovered from Covid-19 and administer that to someone who is sick with Covid-19. And just a pitch out there to everyone, if you've recovered from Covid-19, go donate plasma. We don't know yet whether it's going to be effective, but a lot of doctors are ordering it and there's great demand for the supply, so please go donate.

Mike, we have over 140 clinical trials active and more than 450 in the pipeline. So the pipeline is very robust for new treatments. And one other thing I'd just like to point out about treatments is there's a type of antibody called monoclonal antibody. And that's where you basically copy the natural immunity from someone who has recovered and you can synthetically create an antibody and that's called a monoclonal antibody. It's worked in other infectious diseases in the past. Those clinical trials are well underway, and we have great hope that they'll show a positive effect. Now, we have to wait for the data but by late summer, early fall. And they can act as a bridge to a vaccine because they can be given both as a treatment and provide immunity but they can also be used for prophylaxis to prevent someone from getting sick. Again, we have to wait for the data.

With respect to vaccines, you've seen an incredible effort by U.S. government and again the great private sector we have in this country. Over 20 manufacturers of vaccines are in the FDA with development plans for vaccines. And you've heard recent reports of a number of companies that are going to the late stages, the Phase III studies for vaccines, very soon. That's great news for Americans.

But, Mike, I want to emphasize one point and that is FDA's role in this is to provide assistance so that manufacturers know what is going to be expected in terms of developing, but we are absolutely an independent regulator. And Americans should understand and I hope understand that we will call balls and strikes on the data. Our job is to determine whether a vaccine is safe and effective. We make no pre-judgment about that. We want to see the science and the data. We will look at that in an independent way. And we will make the absolute best decision for the American people about the safety and effectiveness, and I want to assure people that FDA is on the job about that.

VICE CHAIRMAN MICHAEL O'NEILL: Well, thanks for that. You know traditionally I guess the protocols for developing new vaccines take a rather long time. I heard somewhere that four years was sort of the shortest period – I forget which disease that was. Obviously, it would be nice to short-circuit that. And I guess my question to you is, is it likely that we will be able to do that?

DR. STEPHEN HAHN: So I think we've already seen evidence of that. And one of the, Mike, the hazards of this conversation is that when people hear shortcuts, they think, okay, shortcuts in whether it's safe or effective. So I'm going to go back to my first point which is we're not going to take shortcuts at FDA when we look at the data. Where the shortcuts have occurred are on the clinical development as well as the manufacturing side. So you're right. In a typical situation, you test a vaccine in a preclinical setting before you go to humans. Then you submit that data. We say it's okay to go into humans. You do a safety trial. We say that it looks safe. You go into then the efficacy trial, the effectiveness trial. And then you go into this big, large, randomized trial to generate the evidence. And that's a sequential approach.

What the sponsors and manufacturers have done is actually do what's called a platform trial where we can look at a number of different treatments all at the same time which makes it a more efficient approach to actually develop those. We also do what's called seamless, which is that you don't need to take that stop. We can look at everything in real time as we get those data and then move on to the next step more quickly.

And then finally, which is perhaps the most important part, Mike, and this is again where the public-private partnership is so important, what manufacturers have done and what U.S. government has supported is what's called manufacturing at risk. So you're the

CEO of a company, Mike, that's developed a vaccine. You're not going to start manufacturing the vaccine until at the end of the day FDA has seen all the data and said, yes, your vaccine is licensed, it's safe and effective. That takes a couple of years.

If you manufacture at risk, while you're doing your clinical trials you start making sure that you have the manufacturing capacity but also you start manufacturing the vaccine so that you're ready when that decision is made. So if you combined the clinical development, the seamless trial approach, the conversations back and forth with FDA, as well as the manufacturing at risk, what you have is an accelerated timetable. But what you don't have and what's really important is at the end of the day FDA is still going to use its expertise to look at the safety and efficacy of those data. So I'm optimistic about this. I'm encouraged by what I see. But at the end of the day, we'll call the balls and strikes in an objective fashion.

VICE CHAIRMAN MICHAEL O'NEILL: Now, there are a number of efforts underway. I read somewhere more than 150 serious research efforts, many of them overseas. We have invested, I gather, about $5 billion mostly in vaccine research, but plenty going on in Europe and China as well. Is there any way to harmonize approvals between the agencies that would approve in Asia and in Europe and our own? Typically, I guess what I have heard over the years is that the U.S. process is slower than that done in other international markets. Is that a fair summary?

DR. STEPHEN HAHN: Actually, it's the opposite, Mike. So if you look at new drug approvals, for example, about 70% of the new drug approvals in the world, 70% are first done in the U.S. and FDA, and our time to approval is shorter on average than any other regulatory agency in the world. Now that being said, we have Memorandums of Understanding and relationships with all of the really developed world's regulatory agencies. I have a regular conversation with Guido Rasi, who is the Head of the EMA, the European Medicines Agency, and so we're talking all the time. We have a very important harmonization effort across all the medical products. We are committed to this process.

And I can tell you this from FDA's perspective, we will look at data from any source. We will apply our criteria objectively from any source. And so, to me, it's a race to get the vaccine and therapeutics done, but it's not a competition. Because at the end of the day, we want those things available for the American people, the American public, for the world, and we'll take the steps necessary to do that and look at those data. Now, the data have to be robust. The data have to fulfill our criteria that we use, that we consider the gold standard for medical product approval.

VICE CHAIRMAN MICHAEL O'NEILL: Well, that makes sense. Would you want to hazard a guess about when a vaccine would be available to the public, an effective and

safe vaccine?

DR. STEPHEN HAHN: Mike, I'm a cancer doctor. I learned a long time ago that I don't have a crystal ball. You know, Dr. Fauci has been quoted many times saying he's cautiously optimistic. I'm cautiously optimistic. I think the timetable that's been described by Operation Warp Speed is a reasonable one. But it would be inappropriate for me to pre-judge because at the end of the day the American people have to have confidence that FDA and the FDA Commissioner is on top of making an independent regulatory judgment on the data and the science. And again, I know I keep going back to that, but I promise you that we're going to do that. And every one of us, every one of us wants a vaccine tomorrow. And everyone wants 100% vaccine effectiveness tomorrow. Whether we get there will be dependent upon what the data and the science show.

VICE CHAIRMAN MICHAEL O'NEILL: Yes, I mean everyone is certainly looking for rays of sunshine here. The Moderna press release yesterday was interesting. I gather that their 45-person study did demonstrate that antibodies could be developed, but there were several members of that study group that had pretty severe reactions. So we get back to your point about safety.

DR. STEPHEN HAHN: Yes, and Mike, I think there is optimism to have. Because if you think about it, we are further along in vaccine development after first identifying a case

in the U.S. than we have ever been in our history. If you think about the development of therapeutics, this country, the world, has never developed the therapeutics that we have right now, that are available to providers in this space of time and really good data to justify the development of those therapeutics. And the pipeline, I mean you mentioned 150. We're seeing that for sure at FDA. We have, not only over 140 trials that we're overseeing, but over 450 that are in the pipeline, that people are planning. So really an unprecedented effort to get therapeutics out there.

And this is not just something that's going to help us for Covid-19, Mike, this is going to help us for other diseases. This is also going to be a great learning experience for FDA, in particular, I can speak to that. How are we going to accelerate medical product development and getting innovation into the hands of American consumers and providers? There are lessons to be learned from the Covid-19 experience that I think will be really important for all of us.

And just to put a finer point on that, Mike, we have initiated what we're calling a mid-action review. We're bringing in an outside group who is talking to internal stakeholders, will be talking to external stakeholders. What did we get right? What can we do better? And how can we turn these lessons that we've learned into something for the future that makes FDA even better than it has been in the past? Because we cannot let this experience go to waste because we've learned a lot about how we do things and I think

we can really help the American people even more in the future.

VICE CHAIRMAN MICHAEL O'NEILL: Sounds very encouraging. Let me ask you this. Let me make an assumption that you appropriately are unwilling to make, but let's say that we have an effective and safe vaccine the first quarter of next year, how long would it take to inoculate the world with this vaccine? And what priorities would you guess would be made? In other words, which patients would get treated first? And in which countries would they be?

DR. STEPHEN HAHN: So I can speak for U.S. government. CDC is ultimately responsible for vaccine work and the development of a vaccine plan. What I can tell you is that Operation Warp Speed which, as you know, is this program that Congress funded and is at HHS, Health and Human Services, to help accelerate therapeutics and vaccines, Operation Warp Speed is working very closely with us because we're providing technical experience from FDA, but also with CDC in terms of exactly the questions that you're asking. And, of course, we want this vaccine, not just to be available in the U.S. As you point out, we want it around the globe because this is a global problem.

So there's a couple of pieces to this, Mike. Maybe I can dissect a little bit. One is you heard me say that manufacturing at risk is already occurring. So there's a couple of

components to the manufacturing process. It's complicated. It starts with creating the platform for actually manufacturing the vaccine itself. But then you also need the syringes. You need the needles. You need supplies that go into that. So you can imagine setting up a process, a chart – if you will – that will allow you to look at all the steps that need to be done. That has been going on for the last four to six weeks. FDA, for example, has been involved in saying, okay, here's the location, here are the manufacturers of the supplies that you'll need for a vaccine.

Then comes the issue, Mike, of who should get the vaccine and when? So, as a doctor, in my mind – and I'm not speaking for the CDC or federal government right now – I'm thinking to myself, what you'd probably want to do is think, okay, who is the most vulnerable? Who is the most at risk for this? And who is the most at risk for developing severe disease from Covid-19? And as we gain more experience, we're learning that the elderly, those with comorbidities – hypertension, obesity, diabetes seem to be most at risk from severe disease.

Now, we put out guidance about a vaccine so that people would be clear about what sort of studies needed to be done. But the other part of that that was really important is who should be included in the clinical trials? So, we really need vulnerable populations, people who are at risk for severe disease to be included. We need those who are in under-represented groups, under-represented minorities, etc., to be included because

we need to understand the efficacy and the safety of this vaccine in all populations.

So when FDA gets those data, Mike, we'll be able to help the manufacturer figure out what are the indications? Does this work in those vulnerable populations? Does this work in under-represented minority populations? And that will help guide the authorizations that we make about a vaccine, and ultimately that can be used to determine who gets the vaccine first. Again, Mike, really the data and the science and the medicine drive this conversation. It's the way that it should be. And we all want 100% effective vaccine. There's nothing 100% in medicine. I know that from years of experience as a doctor. We want it to be as effective as possible and we very much want it to be effective in those who are most at risk for severe disease.

And I'll put one last point on this, Mike, because it might get lost sometimes in the translation. We said, in our guidance, at the end of the day what we were most interested in was the clinical endpoint of a trial, meaning a vaccine, as you know from the publications you've seen, might elicit, might cause an antibody reaction. And that's great, we want to see that. But at the end of the day, what we want to see is a vaccine either prevent getting a disease or if you get it, it's not severe. It's like the cold. That's what we want to see. So those clinical endpoints are really what we want to see as data coming from these trials. And I believe that's what's most important to the American people and people around the globe.

VICE CHAIRMAN MICHAEL O'NEILL: Yes, that all makes sense. How long will it take to manufacture enough doses to inoculate most of the world?

DR. STEPHEN HAHN: Well, the short answer is it really depends on, well, the short answer is it'll take months to get that. We've got a head start which is great. But obviously we want to ramp up as quickly as possible, and as much as we can do to shorten that. Mike, what we're all hoping for, because, you know, more than 20 manufacturers are in FDA with multiple different trials, what we're hoping is that this will be multiple shots on goal and that we'll have more than one vaccine. In which case, the ramp up will be even more. And it may be that one vaccine we want to target for folks who are the most vulnerable and the other for younger people. I mean I'm speculating here. I'm not saying that's what's going to happen. But you can imagine if you have multiple shots on goal, you'll be able to make those decisions. But even if we have one vaccine, we'll want to ramp that up substantially, and it's why this head start is so important.

VICE CHAIRMAN MICHAEL O'NEILL: Makes sense. As I recall, Operation Warp Speed had the goal of having an effective vaccine, a safe vaccine, out in October, with lots of doses having been manufactured. Is that something that is still in place as projected?

DR. STEPHEN HAHN: I mean I think we have; I think Operation Warp Speed, this is a stretch goal. I mean that would be record time. I, again, don't have a crystal ball. I can't predict what date, what month that will happen. But everyone is really focused on getting this out here as quickly as possible. I've said multiple times, as a cancer doctor, I want to provide hope, and there is great reason for hope. But what I don't want to do is provide false hope because that would be just as bad to provide false hope. So I want to be clear that everyone, 24/7, is working on this. All hands on deck. All resources being brought to bear in this. Great public-private partnership. But we can't make a promise about when it's going to be available.

VICE CHAIRMAN MICHAEL O'NEILL: Yes, that's fair enough. Thank you for that. Let me ask you another question. Not directly related to your responsibilities, but today there was, I guess, a report that the CDC will no longer be the agency that deals with hospitals in terms of patient outcomes and that that will now go to the HHS directly and will not be made public. What's behind that, if you know and have a view?

DR. STEPHEN HAHN: So I don't have any insight into that particular decision. And, of course, we're always cognizant of the burdens that we put on hospitals. Goodness knows they're dealing with enough things right now. But one thing that we've learned, Mike, and I think it's really important to stress is what we've learned is that data, more data, accurate data, is the key to any public health crisis. Frankly, at FDA, for example,

it's the key to everything we do. Modernizing our data, understanding that the data is accurate, that it's in a usable format. Those are critical aspects. I think we've learned over this pandemic that having access to data about the actual disease has been critical to providing information to providers and also the great public sector we have in this country in terms of developing and manufacturing the medical products we need.

And I'll just give you an example. So when this all started, not a whole lot of information was known about transmission. We have learned that Covid-19 affects – from a mortality and severe illness point of view – those who are older and those who are having comorbidities. We've learned from this disease that many younger people, maybe as many as 30% or 40% are asymptomatic when they get infected with this disease. So you can see that access in real time to data gives us much more that we can work with and helps us respond in a much more nimble way. So certainly accessing data from hospitals is critical and we're really happy to partner with them for this.

VICE CHAIRMAN MICHAEL O'NEILL: Dr. Hahn, I'm going to bring a close to this. Thank you for sparing us 30 minutes. I'm sure your schedule is absolutely chockablock. It's been very, very useful and I think, I can say that we're quite lucky to have you in that seat. Thanks.

DR. STEPHEN HAHN: Michael, thank you very much. I really appreciate the

opportunity. It's been an honor to be here. Thank you.